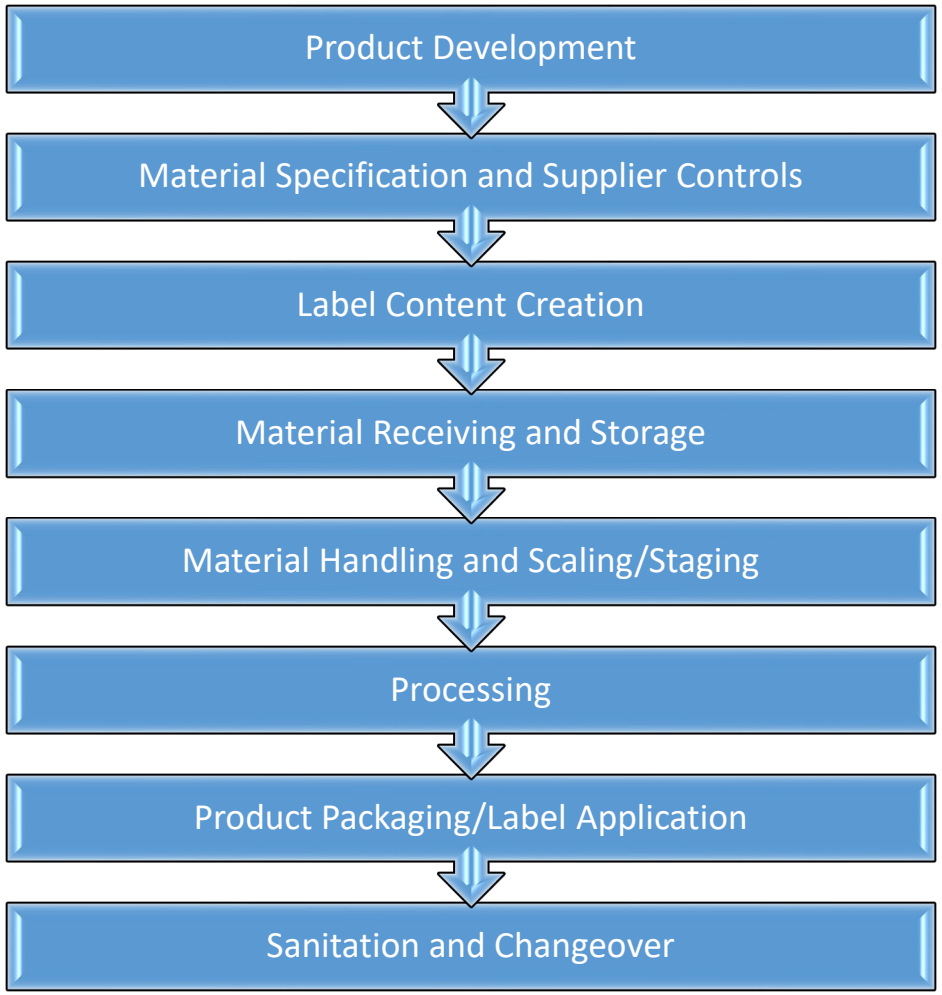
Managing Food Allergens: Receiving, Storage and Handling

Scott Hegenbart
Manager Scientific Affairs

Where this fits

- Determining allergen controls:
  - Map your process flow
  - Identify the potential allergen hazards
  - Devise allergen controls
- Applicable to all preventive control-based plans



FSMA fundamentals

(2) *Food allergen controls.* Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

When in doubt, consult 21 CFR 117.80!

FSMA moment

- 21 CFR 117.80(b)(1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration.

Segregation isn’t as easy as it seems

Retaining segregation

Each of these steps…

- Receiving
- Storage
- Handling

Must maintain…

- Identification
- Segregation

Retaining segregation

- **Receiving**
  - **Inspection**
  - **Identification**
- Storage
- Handling

Inspection

- In addition to checking for integrity and security
- Check raw materials for identification and labeling
- Assure shipment and all pallets meet segregation requirements
- Inspect all shipping units for damage
- Check pre-printed packaging material for accuracy

Managing inspection failure

- Do not accept shipment
- File a request for corrective action with supplier
- This is challenging if the facility runs on just-in-time protocols
- Make sure staff is empowered to act!

Why identify?

- Ingredient declarations are small
- Palletized ingredients may be stacked so ingredient declaration is not visible
- Ingredient may be in a tote or in bulk with no printed label

How to identify?

- Text
- Color
- Symbols or icons

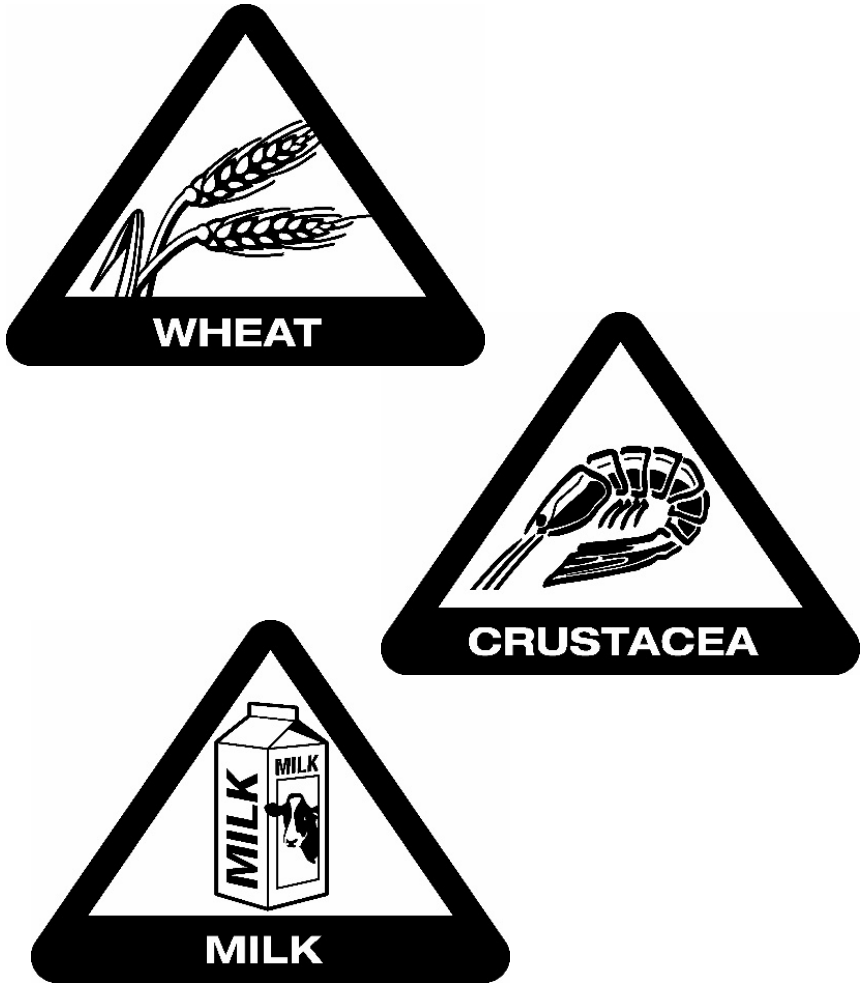
Language and color

Color	English	Spanish	French
Black w/White Lettering	Peanuts	Manĩ	Arachides
Lime Green	Tree Nut	Nueces de árbol	Noix d'arbe
Blue	Fish	Pescado	Poisson
Green	Crustacean Shellfish	Crustáceo/Mariscos	Crustacés/Fruits de Mer
Orange	Milk	Leche	Lait
Pink	Egg	Huevo	Oeuf
Red	Soy	Soya	Soya
Yellow	Wheat	Trigo	Blé
Purple	Sesame	Ajonjoli	Sésame
White w/Red Lettering	Sensitive Ingredients	Ingredientes sensitivos	Ingrédients sensibles

Language and color limitations

- Tools, etc. are limited by color choice
- Labels only have so much room for alternate languages
- Multiple facilities may have different sets of allergens
- Staff may speak a multitude of languages that historically have been less common

Icons and symbols



- Created by International Association for Food Protection
- Available at:

https://www.foodprotection.org/resources/food-allergen-icons/

- May take up significant space on labels for multi-allergen ingredients

Combining techniques

- Text and color
- Text and icons
- Icons and color

How about all three?

Computerized systems

- System-printed handling unit labels
  - Small text
  - No color coding
  - Bar code concerns
- Blank label for color coding
  - Only if text is readable
  - Otherwise, only for short-term situations

FSMA moment, revisited

- Does the receiving process potentially present hazards that may require a preventive control?
- What might happen if a failure occurred at this step?

Retaining segregation

- Receiving
- **Storage**
- Handling

FSMA moment

- 21 CFR 117.80(b)(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact
- 21 CFR 117.80(b)(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.
- 21 CFR 117.80(b)(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

Segregation isn’t as easy as it seems

The sequel…

General warehouse guidelines

- Separate area
  - Room
  - Section
  - Column
  - Floor
- Separate carrier
  - Pallet
  - Tote
  - Other container
- Separate location
  - Store allergens below non-allergens
  - Multi-allergen ingredients lowest of all
  - Maintain sufficient space on floor
- Location identification

General bulk guidelines

- Dedicate tanks or bins
- Non-dedicated vessels
  - Clean
  - Inspect
  - Validation?
  - Document
- Identify
- Lock-out

FSMA moment, revisited

- Is allergen storage potentially a preventive control?
- What might happen if a failure occurred at this step?

Retaining segregation

- Receiving
- Storage
- **Handling**

FSMA moment

- 21 CFR 117.80(c)(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.
- 21 CFR 117.80(c)(5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
- 21 CFR 117.80(c)(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.
- 21 CFR 117.80(c)(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

Raw material handling

- Pulling correct ingredients and packaging
- Scaling and staging ingredients
- Returning ingredients and packaging to warehouse
- Treating rework like an ingredient

Pulling ingredients and packaging

- Pick list based on batch sheet/bill of materials
- Include material identification codes
- Call out ingredient allergens
- Provide access procedure for locked out bulk ingredients

Staging ingredients

- Contain
- Identify
- Transport

Contain

- Color code
- Manage reusable containers
- Single-use containers
- Containers should have a cover or be sealable
- Food handling tools

Identify

- Label all staged materials
- Confirm removal of previous label
- Label should include:
  - Material number or item code
  - Material description
  - Color-coded/icon/multilingual allergen label

Transport

- Dedicate pallets
- Stage ingredients in designated location
- Maintain appropriate spacing if stored on floor

Returning ingredients

- Seal open containers
- Do not mix pallets
- Maintain identification

Rework and WIP

- Treat like ingredient
- Identify appropriately, including color coding
- Store according to allergen content
- Transport appropriately when used

Special situations

- Segregation not always possible
- Allergens pervasive in situations such as:
  - Extremely predominant allergen
  - Extremely difficult to contain
- Dedicating the facility may be best

FSMA moment, revisited

- Is the allergen handling potentially a preventive control?
- What might happen if a failure occurred at this step?

Final words

- Training is vital
  - Document how tasks are done in procedures
  - Train to the procedure
- Re-training to enhance and refresh knowledge
- Documenting training
- Training should include all employees

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